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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/914,913 | 12/17/2001 | Peter Beyer | | 5922 |
| 22847 7590 03/25/2008 SYNGENTA BIOTECHNOLOGY, INC. PATENT DEPARTMENT 3054 CORNWALLIS ROAD P.O. BOX 12257 RESEARCH TRIANGLE PARK, NC 27709-2257 | | | | |
| EXAMINER | | | | |
| KALLIS, RUSSELL | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1638 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/914,913

Applicant(s)

BEYER ET AL.

Examiner

RUSSELL KALLIS

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 32-43 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 32-43 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CC)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 16, 32-43, and 60 are pending and examined.

Claim Rejections - 35 USC § 103

Claims 16, 32-43 and 60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burkhardt P. *et al.*, in RICE GENETICS III; Proceeding of the Third International Rice Genetics Symposium; International Rice Research Institute (IRRI), 1996; Khush G. S. ed., in view of Shewmaker C. in WO 99/07867 published 18 February 1999. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/07/2007.

Applicant's arguments filed 12/07/2007 have been considered but are not deemed persuasive.

Applicant asserts on page 4 of the response that "the Examiner acknowledges that it (i.e. Burkhardt *et al.*) does not teach a bacterial phytoene synthase Burkhardt reference". This is a misrepresentation of the facts. The rejection stated:

"Burkhardt does not teach a bacterial phytoene desaturase encoding sequence fused to a sequence encoding the pea Rubisco small subunit transit peptide; a vector encoding system derived from *Agrobacterium tumefaciens*; or a plant transformed with a bacterial phytoene desaturase encoding sequence."

To make it clear for Applicant, the rejection states that the bacterial phytoene synthase was not fused to the Rubisco transit peptide, or placed in a transformation vector, or taught a plant transformed therewith.

Further, Applicant omitted in their remarks for the record that portion of the rejection that recited the availability of genes from bacteria and plants:

"the availability of genes encoding the four necessary enzymatic activities for beta-carotene biosynthesis in plants and bacteria (page 819, lines 16-22);"

Applicants' remarks on page 4 of the response directed to the use of only the plant phytoene synthase and the bacterial desaturase are misleading in that it suggests that only two activities were required for the production of beta-carotene. It is well known in the art that the bacterial form of the phytoene desaturase comprises four biochemical activities see (Misawa *et al.* 1990; recited on p. 819 line 22 Burkhardt *et al.*; also in Applicants' specification and in Shewmaker) and thus the reference does not teach away. This was already made of record;

" and suggest a strategy for using single genes or combinations of genes from the carotenoid biosynthetic pathway (page 819, lines 27-44); "

Applicant asserts on page 5 of the response that Burkhardt does not teach a method for producing β -carotene in rice but only recites what was the prevailing view in the art. This assertion is contrary to the teachings of Burkhardt. See Burkhardt page 819 lines 4-6 and lines 27-28. "The project aims to initiate carotenoid biosynthesis in the rice endosperm tissue to increase the daily vitamin A uptake of potential vitamin-A deficient people who rely predominantly on rice as a food source. . ." "Our strategy is to produce transgenic rice varieties that contain either single heterologous carotenoid biosynthetic genes or several genes in combination."

Applicants' assertion on page 5 of the response that there is no direct assertion in Shewmaker to combine the specific plant and bacterial genes is not well founded because Shewmaker did reduce to practice dramatically increased production of β -carotene in the

endosperm of *Brassica napus* seeds transformed with the *crtI* gene that Applicant found so useful in engineering increases of β -carotene in rice endosperm.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Applicants' assertion on page 6 lines 3-17 that Shewmaker is transforming a different type of plant and that there is no information that the bacterial enzymes taught by Shewmaker that worked in *Brassica*, a plant that produces beta carotene, would prove successful in rice a plant that does not produce beta carotene in the endosperm is misleading and that Burhardt is deeply engaged in the art of engineering Vitamin A or beta carotene biosynthesis in rice endosperm as argued supra and in the previous office action.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants' assertion that the Examiner has gone outside the art and the knowledge possessed by one of ordinary skill in the art is incorrect because Burkhardt is directed to transformation of rice with carotenoid biosynthetic genes from plants and bacteria; wherein the materials and knowledge for producing beta carotene in plants as broadly claimed or in rice as claimed in claims 40, 43 and 60 are taught in Burkhardt; and wherein one of ordinary skill would have been motivated by the teachings of Burkhardt; where it is demonstrated for the first time that it is in principle possible to engineer a critical step in provitamin A biosynthesis in a non-photosynthetic, carotenoid-lacking plant tissue where those results have important implications for long-term prospects of overcoming worldwide vitamin A deficiency; that the genes encoding the enzymes required for beta-carotene biosynthesis from plants and bacteria were available in the art at the time of filing, as also taught by Shewmaker and Applicant's specification; and that rice endosperm contains GGPP the substrate for phytoene synthase as taught by Burkhardt, and is thus a valuable tool for engineering provitamin A production, and by the success of Burkhardt in transforming rice with phytoene synthase (daffodil) and phytoene desaturase (daffodil) and expressing the plant phytoene synthase (daffodil) in the endosperm of rice seeds resulting in high levels of phytoene, the precursor for phytoene synthase; and by the success of Shewmaker in producing several hundred fold increases of β -carotene in seeds of *Brassica napus* transformed with bacterial phytoene synthase (*crtB*) and bacterial phytoene desaturase (*crtI*) from *Erwinia uredovae*; that one would have had a reasonable expectation of success in transforming a rice plant with a plant phytoene synthase and a bacterial phytoene desaturase; and in producing beta carotene in the endosperm of rice given the success of Shewmaker and Burkhardt.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell Kallis/
Primary Examiner, Art Unit 1638
March 17, 2008